UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

LATIESE MILLS, **Plaintiff,** **v.** **ETHICON, INC.; JOHNSON & JOHNSON; C.R. BARD INC.; DAVOL, INC.; ATRIUM MEDICAL CORPORATION; MAQUET CARDIOVASCULAR, LLC; GETINGE AB; COVIDIEN, INC.; COVIDIEN LLC; COVIDIEN PLC; COVIDIEN AG; SOFRADIM PRODUCTIONS; and JOHN DOE CORPORATIONS 1-100,** **Defendants.**	Civ. No. 17-12624 (KM) (JBC) **OPINION**

KEVIN MCNULTY, U.S.D.J.:

Plaintiff Latiese Mills commenced this personal injury action against defendants Atrium Medical Corporation ("Atrium") and Maquet Cardiovascular, LLC ("Maquet"). Now Before the Court is the motion of Atrium and Maquet for summary judgment. For the reasons expressed below, Atrium and Maquet's motion for summary judgment is **GRANTED in part and DENIED in part**.

I. BACKGROUND

A. Facts[1]

In April 2012, Mills underwent surgery wherein her bowel was improperly attached to her vagina. (Def. St. ¶ 2; Pl. Resp. ¶ 2.) Thereafter, Mills

[1] Certain citations to record are abbreviated as follows:

"DE" = Docket entry number in this case

"Compl." = Mills's Amended Complaint (DE 43)

"Def. Mot." = Atrium and Maquet's Memorandum of Law in Support of their Motion for Summary Judgment (DE 102-1)

underwent corrective surgery involving a midline incision. (*Id.*) A year after Mills's operation, "her incision was tender, the bottom of her incision bled, and it sometimes had a foul odor." (Def. St. ¶ 3; Pl. Resp. ¶ 3.) "A hernia later developed along Plaintiff's incision and, [o]n March [27,] 2013, Plaintiff underwent hernia repair surgery by Dr. Alan Schuricht with ProLite [mesh] placed at the hernia site to complete the repair." (Def. St. ¶ 4; Pl. Resp. ¶ 4.) ProLite is a polypropylene surgical mesh used in hernia repair. (Pl. St. ¶ 27; Def. Resp. ¶ 27.) "The subject ProLite mesh was manufactured by Atrium at Hudson on April 2, 2012, implanted in Plaintiff on March 27, 2013 and explanted on March 31, 2017." (Pl. St. ¶ 39; Def. Resp. ¶ 39.)

Mills's surgical site became infected and, on July 3, 2013, Dr. Schuricht performed surgery to debride the infection. (Def. St. ¶ 10; Pl. Resp. ¶ 10.) "The debridement surgery removed infected abdominal wall tissue and a small portion of ProLite, measuring 1 x 1.5 centimeters of the original 3 x 6 inches." (Def. St. ¶ 12; Pl. Resp. ¶ 12.) Plaintiff alleges that she sustained "seroma,

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"Def. St." = Atrium and Maquet's Statement of Undisputed Facts (DE 102-2)

"Power Decl." = Declaration of Caroline Power in Support of Atrium and Maquet's Motion for Summary Judgment (DE 102-3)

"Pl. Op." = Mills's Memorandum in Opposition to Atrium and Maquet's Motion for Summary Judgment (DE 104)

"Pl. Resp." = Mills's Response to Atrium and Maquet's Statement of Material Facts (DE 104-1 pp. 1–9)

"Pl. St." = Mills's Statement of Additional Material Facts (DE 104-1 pp. 9–20)

"Benak Decl." = Declaration of James D. Benak in Support of Mills's Opposition to Atrium and Maquet's Motion for Summary Judgment (DE 104-2)

"Def. Reply" = Atrium and Maquet's Reply Brief in Support of Motion for Summary Judgment (DE 106)

"Def. Resp." = Atrium and Maquet's Response to Mills's Statement of Additional Material Facts (DE 107)

"Pl. Surreply" = Mills's Surreply in Opposition to Atrium and Maquet's Motion for Summary Judgment (DE 109-2)

infection, additional surgery, scar formation, pain, and hernia recurrence" because of the ProLite mesh. (*See* Def. St. ¶ 6; Pl. Resp. ¶ 6.)

On February 4, 2014, Mills filed a malpractice action in Pennsylvania state court claiming that her 2012 surgeries caused her 2013 hernia surgery and subsequent issues, ongoing abdominal pain and infection, and other damages. (Def. St. ¶ 15; Pl. Resp. ¶ 15; *see* Power Decl. Ex. 5.) In her malpractice action, Mills alleged: "The hernia developed as a consequence of damage to the muscles and fascia in the abdomen as a consequence of the [2012] open laparotomy procedure and erosion of these tissues as a consequence of infection and irritation by contaminants as a result of the colovaginal fistula." (Def. St. ¶ 16; Pl. Resp. ¶ 16.) On November 23, 2015, in relation to the malpractice action, Mills executed a settlement agreement releasing:

> "all [] person . . . whether or not named herein . . . from any and all causes of action, claims and demands of whatsoever kind on account of all known and unknown injuries, losses and damages allegedly sustained by Latiese M. Mills as a result of any conduct and/or action of [named healthcare providers], at any time, including but not limited to any claim arising out of or in any way connected with [Ms. Mills's 2012 abdominal surgeries]. . . . It is expressly understood and agreed that this release and settlement is intended to cover and does cover not only all now known injuries, losses and damages, but any further injuries, losses and damages which arise from, or are related to, any claim which Latiese M. Mills ever had, now has, or may have [regarding her 2012 abdominal surgeries].

(Def. St. ¶ 17; Pl. Resp. ¶ 17.)

B. Procedural History

On November 30, 2017, Mills filed a complaint in New Jersey state court alleging the following claims: (1) negligence; (2) strict products liability – defective design; (3) strict products liability – failure to warn; (4) breach of an express warranty; (5) breach of an implied warranty for a particular purpose; and (6) breach of an implied warranty of merchantability. On December 5, 2017, defendant Covidien Inc. removed the action to this Court, invoking

diversity jurisdiction, 28 U.S.C. § 1332(a). (DE 1). On December 15, 2017, Mills voluntarily dismissed the following defendants: Ethicon, Inc.; Johnson & Johnson; C.R. Bard Inc.; Davol, Inc.; Covidien, Inc.; Covidien LLC; Covidien PLC; Covidien AG; Sofradim Productions; and John Doe Corporations 1-100. (DE 2).

On January 15, 2019, the remaining defendants, Atrium, Maquet, and Getinge AB, filed motions to dismiss. (DE 25, 26.) Atrium and Maquet sought dismissal of the complaint pursuant to Federal Rule 12(b)(6) on the grounds that the complaint failed to meet pleading standards for statement of a claim. They also contended that applicable Pennsylvania substantive law does not recognize strict liability or warranty claims in medical device products liability cases. Getinge AB, the Swedish corporate parent of Atrium and Maquet, contended that service was defective and that it was not subject to personal jurisdiction in New Jersey.

On August 27, 2019, I granted the motion to dismiss. (DE 38.) I dismissed, with prejudice, Mills's claims of strict liability for defective design (second count); strict liability for failure to warn (third count); breach of the implied warranty of fitness for a particular purpose (fifth count); and breach of the warranty of merchantability (sixth count). I dismissed, without prejudice, Mills's claims of negligence and breach of express warranty (first and fourth counts). I also concluded that Mills's service on Getinge AB was deficient.

On November 8, 2019, Mills filed an amended complaint naming only Atrium and Maquet (as well as John Doe Corporations 1-100) as defendants. (DE 43.) The amended complaint asserts two claims: negligence (first count) and breach of express warranty (second count).

On August 12, 2022, Atrium and Maquet filed a motion for summary judgment and a motion to exclude the opinions and testimony of Mills's expert Dr. Paul J. Cohen. (DE 102, 103.) On March 1, 2023, the motion for summary judgment was stayed pending decision on the motion in limine to exclude Dr. Cohen's evidence. (DE 112.) On March 28, 2023, Judge Clark issued an opinion and order denying defendants' motion to exclude. (DE 113.)

Accordingly, Judge Clark reinstated the pending motion for summary judgment (DE 124), which is fully briefed and ripe for decision. (*See* DE 102, 104, 106, 107, 109, 129.)

II. LEGAL STANDARD

Summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is material if it "might affect the outcome of the suit under the governing law" and a dispute about a material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Disputes over irrelevant or unnecessary facts will not preclude the Court from granting a motion for summary judgment. *See id.*

A party moving for summary judgment has the initial burden of showing the basis for its motion and must demonstrate that there is an absence of a genuine issue of material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). "A party asserting that a fact [is not] genuinely disputed must support the assertion by . . . citing to particular parts of materials in the record, including depositions, documents . . ., affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials." Fed. R. Civ. P. 56(c)(1)(A). After the moving party adequately supports its motion, the burden shifts to the nonmoving party to "go beyond the pleadings and by her own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial." *Celotex*, 477 U.S. at 324 (internal quotation marks omitted).

"[W]ith respect to an issue on which the nonmoving party bears the burden of proof . . . the burden on the moving party may be discharged by 'showing' — that is, pointing out to the district court — that there is an absence of evidence to support the nonmoving party's case." *Id.* at 325. Once the moving party has met that threshold burden, the non-moving party "must

do more than simply show that there is some metaphysical doubt as to material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). The opposing party must present actual evidence that creates a genuine issue as to a material fact for trial. *Anderson*, 477 U.S. at 248.

Unsupported allegations, subjective beliefs, or argument alone cannot forestall summary judgment. *See Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 888 (1988) (nonmoving party may not successfully oppose summary judgment motion by simply replacing "conclusory allegations of the complaint or answer with conclusory allegations of an affidavit."); *see also Brewer v. Quaker State Oil Ref. Corp.*, 72 F.3d 326, 330 (3d Cir. 1995) ("[T]he nonmoving party creates a genuine issue of material fact if it provides sufficient evidence to allow a reasonable jury to find for him at trial."). Thus, if the nonmoving party fails "to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial . . . there can be 'no genuine issue of material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *Katz v. Aetna Cas. & Sur. Co.*, 972 F.2d 53, 55, n.5 (3d Cir. 1992) (quoting *Celotex*, 477 U.S. at 322-23).

"In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the nonmoving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'" *Marino v. Indus. Crating Co.*, 358 F. 3d 241, 247 (3d Cir. 2004) (quoting *Anderson*, 477 U.S. at 255)). In that respect, the Court's role in deciding a motion for summary judgment is simply "to determine whether there is a genuine issue for trial." *Anderson*, 477 U.S. at 249. Ultimately, there is "no genuine issue as to any material fact" if a party "fails to make a showing sufficient to establish the existence of an element essential to that party's case." *Celotex*, 477 U.S. at 322.

III. DISCUSSION

A. Mills's 2015 Settlement

Defendants assert that summary judgment should be granted in their favor because Mills's claims are barred by a release agreement she signed in November 2015 in a separate malpractice action. (Def. Br. p. 19.)

In April 2012, Mills underwent surgery involving the bowel and vagina. (Def. St. ¶ 2; Pl. Resp. ¶ 2.) A hernia developed, and in March 2013, Mills underwent further surgery, which included implantation of ProLite mesh. (Def. St. ¶¶ 3–4; Pl. Resp. ¶¶ 3–4.) On February 4, 2014, Mills filed a malpractice action, wherein she claimed that "her 2012 surgeries caused her 2013 hernia surgery and subsequent issues, ongoing abdominal pain and infection, and other damages." (Def. St. ¶ 15; Pl. Resp. ¶ 15.)

On November 23, 2015, Plaintiff executed a settlement agreement in the malpractice action. Atrium and Maquet, although they were not parties to the malpractice action, argue that the settlement agreement unambiguously releases them from all of Mills's claims in the current action. (Def. Mot. p. 19.) Plaintiff responds that the subject matter of the malpractice action is not sufficiently related to the later infection, which she alleges was caused by ProLite mesh. (Pl. Op. p. 19.) That ProLite mesh, Mills explains, was inserted as part of the 2013 hernia surgery, which occurred after the initial 2012 surgery that was at issue in the malpractice action. (*Id.* p. 20.)

"In Pennsylvania, it is well settled that the effect of a release is to be determined by the ordinary meaning of its language. The enforceability of settlement agreements is governed by principles of contract law. Courts will enforce a settlement agreement if all its material terms have been agreed upon by the parties." *Pennsbury Vill. Assocs., LLC v. Aaron McIntyre*, 11 A.3d 906, 914 (Pa. 2011) (internal citations and quotation marks omitted). "A settlement agreement will not be set aside absent a clear showing of fraud, duress, or mutual mistake." *Id.*

Additionally, "[a] long line of Pennsylvania cases has held that a release covers only those matters which may be fairly said to have been within the contemplation of the parties when the release was given." *Bowman v. Sunoco, Inc.*, 65 A.3d 901, 909 (Pa. 2013) (quoting *Restifo v. McDonald*, 230 A.2d 199, 201 (Pa. 1967)). The Court should "interpret a release so as to discharge only those rights intended to be relinquished. The intent of the parties must be sought from a reading of the entire instrument, as well as from the surrounding conditions and circumstances." *Vaughn v. Didizian*, 648 A.2d 38, 40 (Pa. Super. Ct. 1994); *see also Fortney v. Callenberger*, 801 A.2d 594, 597 (Pa. Super. Ct. 2002) ("[R]eleases are strictly construed so as not to bar the enforcement of a claim that had not accrued at the date of the execution of the release."). Furthermore, "[w]aivers which release liability for actions not accrued at the time of the release are generally only invalid if they involve future actions entirely different than ones contemplated by the parties at the time of the release." *Bowman*, 65 A.3d at 909.

Under the above principles, Atrium and Maquet's reliance on *Buttermore v. Aliquippa Hospital*, 561 A.2d 733 (Pa. 1989) and *Slater v. Saint Vincent Health Ctr.*, No. 896 WDA 2016, 2017 WL 1041384 (Pa. Super. Ct. Mar. 17, 2017), is misplaced. (*See* Def. Mot. pp. 20–22.)

In *Buttermore*, the plaintiff suffered injuries in a car accident and was taken by ambulance to a hospital. 561 A.2d at 734. The plaintiff signed an agreement with the insurer of the other driver in the accident. The agreement with the insurance company released "any and all other persons, associations and/or corporations, whether known or unknown . . . present and future claims, . . . for or because of any matter or thing done, omitted or suffered to be done, on account of or arising from damage to property, bodily injury or death resulting or to result from [the car accident at issue]." *Id.* Thereafter, the plaintiff filed a separate lawsuit against the hospital where he received treatment for his accident-related injuries. *Id.* at 734–35. The plaintiff asserted that his claims against the hospital should not be barred because it was not

his intent when signing the release agreement to release the hospital from liability. *Id.* at 735. That reasoning was found insufficient, and the court determined that his claims were barred by the language of the release agreement. *Id.*

In *Slater*, the plaintiff executed an agreement releasing "named and unnamed individuals and entities from any and all actions, causes of action, claims or demands . . . for any known or unknown injuries, losses or damages [they] sustained that were related in any way" to the claim at issue. 2017 WL 1041384, at *13 (internal quotation marks omitted). Thereafter, the plaintiff filed another lawsuit, wherein the defendants raised the release as a bar. The trial court determined that, because the claims in the second lawsuit were related to the released claims in the first lawsuit, and because the plaintiff had expressly asserted the current claims in the prior action, those claims were barred under the release agreement. *See id.* *7, *13 n.3.

Buttermore and *Slater* have a common, determinative factor. There, the claims in the plaintiffs' later-filed actions were (a) apparent to the plaintiffs at the time they executed their release agreements and (b) closely related to the claims that they had released. Pennsylvania courts have declined to enforce a release agreement, however, when those factors were not present—*i.e.,* when the new claims were not apparent at the time of the release and were sufficiently distinct from the old claims. In that connection, subsequent intervening acts of negligence have been found particularly significant.

In *Vaughn*, for example, the plaintiff executed a general release of liability for all claims resulting from an automobile accident. 648 A.2d at 39. About seven months later, the plaintiff underwent surgery for those injuries. *Id.* The plaintiff then filed a malpractice lawsuit alleging that the doctor negligently performed the surgery. *Id.* at 40. The court held that the release did not bar the plaintiff's claims against the doctor because the doctor's negligent treatment of her injuries, which had not occurred or accrued at the time of the release, could not have been contemplated by the parties. *Id.* at 41. As one court has

described the situation in *Vaughn*, "the claim alleged to have been waived was a step removed from the actual release at issue." *Sauer Inc. v. Honeywell Bldg. Sols. SES Corp.*, 742 F. Supp. 2d 709, 718 (W.D. Pa. 2010).

Similarly, in *Youngren v. Presque Isle Orthopedic Group, Inc.*, the plaintiff was involved in a car accident and underwent low lumbar surgery to address her injuries. 876 F. Supp. 76, 77 (W.D. Pa. 1995). Thereafter, the plaintiff executed a general release form releasing the driver and "all other persons" from all liability related to the accident. *Id.* A few years later, the plaintiff was involved in a second car accident and sought medical treatment. *Id.* at 78. During her consultation, she discovered that the doctor who had performed her low lumber surgery following the first accident had done so on the wrong side of her spine, and she filed a malpractice lawsuit against that doctor. *Id.* The court determined that the plaintiff's claim did not arise from the accident covered by the release but rather from a *separate* tort: the injury caused by the doctor when he performed the low lumbar surgery on the wrong side of her spine. *Id.* at 79. The court also determined, separately and in the alternative, that a jury could conclude that the claim at issue did not accrue until years later when plaintiff discovered the doctor's negligence. *Id.* at 80.

In this case, Mills executed an agreement in November 2015 releasing "any claim arising out of or in any way connected with" her 2012 abdominal surgeries and "any claim which [Mills] ever had, now has, or may have" regarding those 2012 surgeries. (Def. St. ¶ 17; Pl. Resp. ¶ 17.) Now it is true that Mills underwent her hernia repair surgery in March 2013, prior to executing the release agreement. However, there is no indication in the release agreement or the surrounding circumstances of the prior lawsuit that the parties contemplated that the settled dispute concerning Mills's 2012 surgery would encompass a claim of negligence against the manufacturer of a mesh product used in a separate hernia surgery almost a year later.[2] As in *Youngren*,

[2] Dr. Schuricht's deposition testimony also indicates that he did not believe that Mills's 2013 hernia repair surgery was a continuation of her 2012 surgery:

Mills's injury resulting from the ProLite mesh is separate from her 2012 abdominal surgery and is, therefore, not covered by the language of the release agreement.[3]

Summary judgment is denied on this ground.

B. Statute of Limitations

1. Negligence Claims

Defendants move for summary judgment on Mills's negligence claims, asserting that they are barred by the applicable statute of limitations. (Def. Br. p. 14.)

Pennsylvania has a two-year statute of limitations for suits alleging personal injury. 42 Pa. Const. Stat. Ann. § 5524. Generally, "a cause of action accrues, and thus the applicable limitations period begins to run, when an injury is inflicted." *Wilson v. El-Daief*, 964 A.2d 354, 361 (Pa. 2009).

The running of the limitations period may be delayed, however, under Pennsylvania's "discovery rule." The discovery rule, similar to that of New Jersey, provides that the limitations period does not begin to run "until the plaintiff discovers, or reasonably should discover, that she has been injured

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> Q. Do you mean to say that your surgery was a continuation of the previous surgery?
>
> A [by Dr. Schuricht]. No. . . .
>
> Q. . . . [I]f there was malpractice that was committed in the first surgery, that certainly would not be attributable to you in the second surgery, would it? . . .
>
> A. Are you asking me am I responsible for a complication in an operation I was not at?
>
> Q. Correct.
>
> A. I would hope not.

(Benak Decl. Ex. 22, Dr. Schuricht Dep. Tr. 102:19–103:12.)

[3] In the alternative, there is an argument that Mills's claims against Atrium and Maquet had not accrued at the time she executed the release agreement. The accrual of Mills's claims will be addressed below in connection with the statute of limitations. *See* Section III.B.1.

and that her injury has been caused by another party's conduct." *Id.* at 361–62. Reasonable diligence is an objective inquiry, but one which includes to some degree "the difference[s] between persons and their capacity to meet certain situations and the circumstances confronting them at the time in question." *Fine*, 870 A.2d at 858 (quoting *Crouse v. Cyclops Indus.*, 745 A.2d 606, 611 (Pa. 2000)). Thus, "reasonable diligence is not an absolute standard, but is what is expected from a party who has been given reason to inform [her]self[4] of the facts upon which [her] right to recovery is premised." *Id.*

"[T]he determination concerning the plaintiff's awareness of the injury and its cause is fact intensive, and therefore, ordinarily is a question for a jury to decide." *Wilson*, 964 A.2d at 362 (citing *Fine*, 870 A.2d at 858). However, "courts may resolve the matter at the summary judgment stage where reasonable minds could not differ on the subject." *Id.*; *see also Fine*, 870 A.2d at 858–59; *Adams v. Zimmer US, Inc.*, 943 F.3d 159, 167–68 (3d Cir. 2019) (reversing and remanding the district court's grant of summary judgment on statute of limitations grounds because factual disputes remained concerning application of Pennsylvania's discovery rule, which needed to be resolved by the jury). "It is the party that asserts application of the discovery rule that bears the burden of proving that reasonable diligence was exercised." *Nicolaou v. Martin*, 195 A.3d 880, 893 (Pa. 2018).

Mills filed this second action on November 30, 2017. As relevant here, she asserted negligence against the manufacturer of the ProLite mesh that had been used in her hernia repair surgery on March 27, 2013. Under the general rule, Mills's claims would be barred by the statute of limitations because the injury-causing event occurred outside the two-year limitations period (*i.e.,* before November 30, 2015). However, Mills relies on the discovery rule, asserting that her discovery of her 2013 injury was reasonably delayed under

[4] As the plaintiff is female, I have attempted where practicable to substitute gendered pronouns to clarify the application of quoted legal standards to her case.

the circumstances. Atrium and Maquet assert that the discovery rule does not save Mills's claims for three reasons, discussed below.

First, Atrium and Maquet argue that the statute of limitations began to run on Mills's claim in July 2013, when Dr. Schuricht performed surgery to debride Mills's infected surgical site. (Def. Br. p. 18; *see* Pl. Resp. ¶ 10.) Atrium and Maquet rely on Mill's deposition testimony, wherein she was asked "Did you believe [in July 2013] that the mesh was causing your injuries?" to which she responded, "Yes." (Def. Br. p. 17 (quoting Power Decl. Ex. 1, Mills Dep. Tr. 176:23-177:1); *see also* Pl. Resp. ¶ 11.) Atrium and Maquet cite three cases for the proposition that "[i]n cases involving surgical mesh and Pennsylvania's discovery rule, courts have held claims accrue at the latest when the plaintiff undergoes a subsequent surgery to address mesh-related complications": *Kennedy v. Ethicon, Inc.*, No. 20-cv-185, 2020 WL 4050459 (E.D. Pa. July 20, 2020); *Soutner v. Covidien, LP*, No. 17-cv-2178, 2019 WL 3801438 (M.D. Pa. Aug. 13, 2019); *Hartey v. Ethicon, Inc.*, No. 04-cv-5111, 2006 WL 724554 (E.D. Pa. Mar. 20, 2006).

Mills responds that she "was not made aware that the cause of her injuries could be the ProLite mesh until Spring 2017" when she "saw an advertisement on television regarding defective mesh." (Pl. Op. p. 18; Benak Decl. Ex. 37, Mills Aff. ¶ 8.) Mills explains in her affidavit that "[n]o treating physician has told me that the mesh device implanted in me was faulty or non-sterile or linked [to] my symptoms" and she "was not aware before [March or April 2017] that any of [her] symptoms could be a result of *faulty mesh from the manufacturer* rather than just [her] body's reaction to the mesh surgery." (Benak Decl. Ex. 37, Mills Aff. ¶¶ 7–8 (emphasis added).) Mills asserts that "her doctor assured her that the mesh was not causing her problem." (Pl. Surreply p. 5.) In support, she cites her own deposition testimony describing her doctor's advice in connection with the July 2013 debridement surgery:

> Q. Before you had this debridement surgery, did you talk to Dr. Schuricht about the surgery?
>
> A [Mills]. Yes.

> Q. What did you talk about?
>
> A. I was asking him why the drains kept falling out and why I kept being in so much pain. And he told me he wanted to do a debridement surgery to wash out the area. And I told him -- I asked did he think it was coming from the mesh; and if it was, could he just take the mesh out.
>
> Q. And what was his response to that question?
>
> A. No, he didn't want to take the mesh out. He wanted to do the debridement and wash around the surgical site and area where the mesh was at.
>
> Q. Did you believe at that point in time that the mesh was causing your injuries?
>
> A. Yes.
>
> Q. When did you first start thinking that the mesh was the cause of your injuries?
>
> A. When the drains kept falling out. When I kept having so much pain. And that's it.

(Benak Decl. Ex. 36, Mills Dep. Tr. 176:5–177:7.)

The record might (or might not) support the conclusion that the July 2013 debridement surgery addressed infection complications that were *in fact* caused by the ProLite mesh. Contrary to Atrium and Maquet's position, however, undergoing corrective surgery does not necessarily place a plaintiff on notice for statute of limitations purposes. Rather, the court must consider the facts and circumstances of the plaintiff's situation, and it cannot do so in a vacuum. *See Nicolaou*, 195 A.3d at 894. Patients are of course aware of their symptoms, but they are often ill-equipped to assess the medical causes of them, and must therefore rely on medical advice. *See Adams*, 943 F.3d at 165 (citing *Nicolaou*, 195 A.3d at 893). Accordingly, a court considering the applicability of the discovery rule must take into account what the patient was being told by her doctors.

For example, in *Nicolaou*, the plaintiff suffered from symptoms that she suspected were caused by Lyme disease. *Id.* at 883. However, the plaintiff's

doctors told her that she did not have Lyme disease and instead diagnosed her with and treated her for multiple sclerosis. *Id.* at 883–84. During that treatment, the plaintiff's symptoms continued. *Id.* When the plaintiff was finally diagnosed with and treated for Lyme disease, her symptoms began to improve. *Id.* at 885. The plaintiff filed a medical malpractice action against the healthcare providers who failed to diagnose and treat her Lyme disease. *Id.* at 882. Without the benefit of the discovery rule, the plaintiff's claims would have been time barred. However, when considering all of the circumstances of the plaintiff's case, including that her prior doctors advised her that she did not have and failed to treat her for Lyme disease, the court held that it was for the jury to decide whether it was reasonable for the plaintiff to not have suspected that she had Lyme disease at an earlier date. *Id.* at 894–95.

Mills testified that she believed or suspected in July 2013 that her mesh was the cause of her injuries. When she raised the issue with her doctor, however, he informed her that debridement surgery and washing of the site, not removal of the mesh, was called for. Dr. Schuricht, who performed the debridement, testified that "the infection could not have originated with Plaintiff's ProLite mesh because, if it had, more of the mesh would have required removal."[5] (Def. St. ¶ 13; Pl. Resp. ¶ 13.) Mills also stated that no treating physician had informed her that her mesh device was causing her injuries and she believed that her injuries were simply the result of her body not reacting well to the surgery. (Mills Aff. ¶¶ 7–8.) As the Third Circuit has recognized, "a lay person is only charged with the knowledge communicated to him or her by the medical professionals who provided treatment and diagnosis." *Adams*, 943 F.3d at 165 (quoting *Nicolaou*, 195 A.3d at 893). To "discover" that her infection resulted from the mesh, Mills would have needed, in effect, to override her physician's opinion with her own. Applying a summary

[5] Mills's July 2013 debridement surgery removed only "a small portion of ProLite, measuring 1 x 1.5 centimeters of the original 3 x 6 inches." (Def. St. ¶ 12; Pl. Resp. ¶ 12.) Whether that fact rebuts causation may present an issue on the merits.

judgment standard, I cannot say that the state of her knowledge does not present a factual issue.

The three cases cited by Atrium and Maquet are not to the contrary, because those plaintiffs did not receive incorrect or unclear information from their doctors. In *Kennedy*, the plaintiff's doctor informed her that her injuries were related to her implanted mesh device and, during one medical visit, the plaintiff viewed through a camera that her injuries were caused by the mesh device. 2020 WL 4050459, at *13. In *Soutner*, the plaintiff suffered severe inflammation at the site of his mesh device implant and ultimately had the mesh removed, along with his vas deferens. 2019 WL 3801438, at *2. And, in *Hartey*, following surgery, the plaintiff was advised that she had "massive scar tissue" and learned that the scarring was "secondary to the use of Mersilene mesh." 2006 WL 724554, at *3. As of the date they received such unequivocal advice from their physicians, those plaintiffs indisputably were on reasonable notice that their mesh devices caused their injuries, and those courts so ruled. Not so in Mills's case.

Second, Atrium and Maquet rely on the "sham affidavit" doctrine. (*See* Def. Reply pp. 1–4.) According to Atrium and Maquet, Mills is attempting to contradict her deposition testimony that she believed in July 2013 that her mesh was causing her injuries by submitting an affidavit stating that she did not know that her mesh was causing her injuries until Spring 2017. (*Compare* Benak Decl. Ex. 36, Mills Dep. Tr. 176:5–177:7, *with* Ex. 37, Mills Aff. ¶ 8.) Their reliance on the "sham affidavit" doctrine is misplaced. A sham affidavit is "a contradictory affidavit that indicates only that the affiant cannot maintain a consistent story or is willing to offer a statement solely for the purpose of defeating summary judgment." *Jiminez v. All American Rathskeller, Inc.*, 503 F.3d 247, 253 (3d Cir. 2007). For the reasons expressed above, in the context of the medical advice Mills was receiving, the inconsistencies between the two statements may provide fodder for cross-examination, but are not so

contradictory as to suggest bad faith. I decline to apply the sham affidavit doctrine.

Third, Atrium and Maquet assert that, even if Mills was not aware of the cause of her injuries in July 2013, she was surely aware of them when she filed her malpractice lawsuit on February 4, 2014. (Def. Br. p. 18.) Defendants acknowledge, however, that Mills filed her malpractice action to recover damages she sustained during her 2012 surgery; the malpractice complaint does not mention ProLite mesh or name any of the defendants in this action. (*See id.*) There is nothing in the malpractice complaint or release to indicate that Mills then knew that the ProLite mesh was causing her injuries. Therefore, I decline to hold that the statute of limitations began to run on the date that Mills filed her malpractice complaint in February 2014.

* * *

There exists a genuine dispute of material fact regarding the date on which Mills knew or should have known that her injuries were caused by Atrium and Maquet's alleged negligence. *See Adams*, 943 F.3d at 163, 167. For the above reasons, Atrium and Maquet's motion for summary judgment on Mills's negligence claims based on the statute of limitations is denied.

2. Breach of Express Warranty Claim

Defendants also move for summary judgment on Mills's breach of express warranty claim, claiming it is barred by the statute of limitations. According to Atrium and Maquet, Mills's express warranty claim accrued as soon as she underwent her hernia repair surgery in March 2013 because an express warranty claim accrues "when tender of delivery is made." (Def. Br. pp. 13–14.) Additionally, Atrium and Maquet assert that they never made any express warranty to Mills, let alone a warranty extending to future performance. (*Id.* p. 14.)

Mills responds that, because Atrium and Maquet warranted "the future performance of the goods," her cause of action did not accrue until she discovered, or should have discovered, the breach. (Pl. Op. p. 24.) Mills asserts

that the discovery rule applies to her breach of warranty claim because her mesh was designed as a permanent implant. (*Id.* p. 25.)

In Pennsylvania, the statute of limitations for a breach of warranty is four years. 13 Pa. Cons. Stat. Ann. § 2725(a). "In cases involving the implantation of a medical device, a breach of warranty cause of action accrues on the date the device is implanted." *Drumheller v. Johnson & Johnson*, No. 20-cv-6535, 2021 WL 1853407, *13 (E.D. Pa. May 10, 2021); *Goodling v. Johnson & Johnson*, No. 21-cv-82, 2022 WL 414285, at *11 (M.D. Pa. Feb. 10, 2022). The Pennsylvania statute contains an exception "where a warranty explicitly covers future performance of the goods, in which case a cause of action accrues when the breach is or should have been discovered." *White v. Hon Co.*, 520 F. App'x 93, 94 (3d Cir. 2013) (citing 13 Pa. Cons. Stat. Ann. §§ 2725(a), (b)). The "future performance" exception reads as follows:

> A breach of warranty occurs when tender of delivery is made, except that where a warranty explicitly extends to future performance of the goods and discovery of the breach must await the time of such performance the cause of action accrues when the breach is or should have been discovered.

13 Pa. Cons. Stat. Ann. § 2725(b). "Except for explicit warranties of future performance, the statute expressly rejects a discovery rule similar to the one that has been developed for personal injury actions." *O'Brien v. Eli Lilly & Co.*, 668 F.2d 704, 711 (3d Cir. 1981).

The focus of the exception "is not on what is promised, but on the duration of the promise—*i.e.*, the period to which the promise extends." *Nationwide Ins. Co. v. Gen. Motors Corp./Chevrolet Motor Div.*, 625 A.2d 1172, 1176 (Pa. 1993) (citation omitted). A defendant's express warranty that a medical device is a "permanent" implant may establish that the warranty extends to future performance. *See Goodling*, 2022 WL 414285, at *12; *McLaughlin v. Bayer Essure, Inc.*, No. 14-cv-7316, 2019 WL 1382710, at *8 (E.D. Pa. Mar. 27, 2019). However, because a warranty extension is "an exception to the general rule," it must be "strictly construed." *Zawadzki v.*

Ethicon, Inc., No. 92-cv-6453, 1994 WL 77350, at *3 (E.D. Pa. Mar. 11, 1994). Thus, "a bare statement of how a good will perform after delivery does not constitute an explicit extension forward," particularly where it "fails to state clearly and unambiguously a period of time during which the warrant[y] will be in force." *Id.* at *5 (citing *Nationwide*, 625 A.2d at 1176 and *Patton v. Mack Trucks, Inc.*, 519 A.2d 959, 964 (Pa. Super. Ct. 1986) (additional citation omitted)).

Here, Mills's mesh device was implanted in March 2013. Therefore, the statute of limitations on Mills's breach of express warranty claim expired in March 2017, before the filing of this action—unless the future-performance exception applies. In order for that exception to apply, Atrium and Maquet must have made an explicit warranty of future performance. Mills asserts that they did because "this mesh was designed as a permanent implant." (Pl. Op. p. 25.)

"Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." 13 Pa. Cons. Stat. Ann. § 2313(a). A promise is the "basis of the bargain if the plaintiff can prove 'that she read, heard, saw or knew of the advertisement containing the affirmation of facts or promise.'" *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 501 (W.D. Pa. 2012) (quoting *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 752 (W.D. Pa. 2004)).

Thus, Pennsylvania law requires explicitness in the making of an express warranty: "Absent a demonstration that a promise or affirmative statement was made, how or by whom the promise was made, or what was in fact promised, a claim for breach of express warranty is not sufficiently pled." *Gross*, 858 F. Supp. 2d at 501–02. As I stated in my motion to dismiss opinion, "[a] plaintiff bringing an express warranty claim is saying that she bought the product based on a statement or promise by the defendant that turned out to be untrue. It is not too much to expect the plaintiff to identify that statement or

promise." (DE 38 p. 34.) Fact discovery is now complete, and no such explicit statement or promise has emerged from the evidence.

In *Drumheller*, the plaintiff alleged that the defendant warranted, among other things, that the plaintiff's pelvic mesh product "will permanently cure or alleviate" her medical condition and "would not need to be partially removed." 2021 WL 1853407, at *14. The court nevertheless determined that the plaintiff failed to allege an express warranty because she did not "provide the specific warranties on which she allegedly relied" and did not "allege the specific materials containing these warranties, nor [did] she allege how she became aware of these materials." *Id.* at *15. Courts have also found that a warranty that a suture will provide "lasting strength" or a warranty that a hip implant "would not fail" did not qualify as extended warranties under Pennsylvania law. *See Zawadski*, 1994 WL 77350, at *5; *Horsmon v. Zimmer Holdings, Inc.*, No. 11-cv-1050, 2012 WL 423434, at *3–*5 (W.D. Pa. Feb. 8, 2012).

Like the plaintiff in *Drumheller*, Mills fails to point to any specific warranty or statement on which she relied that stated any particular duration, let alone permanence. (*See* Pl. St. ¶¶ 5–9, 16, 35–37, 49–53, 57.) The testimony and other documents to which Mills cites do not contain any representation made by defendants to Dr. Schuricht or any representation "that the ProLite mesh used in [Plaintiff's] surgery was intended to be permanent." (*See* Pl. St. ¶ 53; Benak Decl. Ex. 22, Dr. Schuricht Dep. Tr. 16:14-20:19; Ex. 31, Atrium's mesh device Instructions for Use (hereinafter, "IFU"); Ex. 27 p. 6, LyondellBasell Product Stewardship Bulletin (stating that the polypropylene used in the ProLite mesh "may not be used in . . . applications involving permanent implantation into the body").) Because Mills fails to identify an explicit warranty of future performance made by Atrium or Maquet, plaintiff's breach of express warranty claim is barred by the statute of limitations.

Therefore, summary judgment is granted in favor of Atrium and Maquet on the breach of express warranty claim (Count Two).

C. Merits of the Remaining Claims

The negligence claim encompasses two alternative theories. Defendants' motion for summary judgment is denied as to the claim of failure to warn, but granted as to the claim of defective design.

1. Negligent Failure-to-Warn Claim

Defendant moves for summary judgment on Mills's negligent failure-to-warn claim for lack of evidence of causation. (Def. Br. p. 9.)

Under Pennsylvania law, to maintain a negligence claim, a plaintiff must show (1) that the defendant had a duty "to conform to a certain standard of conduct"; (2) that the defendant breached the duty; (3) that such breach caused the injury in question; and (4) actual loss or damage. *Phillips v. Cricket Lighters*, 841 A.2d 1000, 1008 (Pa. 2003). "[A] cause of action for negligence must fail unless defendant's conduct is shown to have been the . . . cause of plaintiff[']s injury." *Kester v. Zimmer Holdings, Inc.*, No. 10-cv-523, 2010 WL 2696467, at *6 (W.D. Pa. June 16, 2010) (quoting *Long v. Krueger, Inc.*, 686 F. Supp. 514, 517 (E.D. Pa. 1988)). "[A]bsent such identification, there can be no allegations of duty, breach of duty or legal causation, and hence there can be no liability." *Id.* (citing *Cummins v. Firestone Tire & Rubber Co.*, 495 A.2d 963, 967–68 (Pa. Super. Ct. 1985)).

To establish proximate causation, a plaintiff asserting a failure-to-warn claim must demonstrate that the "user of the product would have avoided the risk had he been advised of it by the seller." *Jeter v. Brown & Williamson Tobacco Corp.*, 113 F. App'x 465, 467–68 (3d Cir. 2004). The "evidence must be such as to support a reasonable inference, rather than a guess," that an adequate warning would have prevented the injury. *Staymates v. ITT Holub Indus.*, 527 A.2d 140, 147 (Pa. Super. Ct. 1987). For a negligent failure-to-warn claim, a plaintiff "must further establish proximate causation by showing that had defendant issued a proper warning to the learned intermediary, he would have altered his behavior and the injury would have been avoided." *Demmler v. SmithKline Beecham Corp.*, 671 A.2d 1151, 1155 (Pa. Super. Ct. 1996) (quoting

Mazur v. Merck & Co. Inc., 742 F. Supp. 239, 262 (E.D. Pa. 1990)). "Summary judgment is properly granted on a failure to warn claim where the record 'is devoid of evidence to support [the] argument that a different warning would have altered [the physician's] prescribing methods . . . .'" *In re Avandia Mktg., Sales Pracs. & Prod. Liab. Litig.*, 639 F. App'x 874, 878 (3d Cir. 2016) (quoting *Lineberger v. Wyeth*, 894 A.2d 141, 150 (Pa. Super. Ct. 2006); *Demmler*, 671 A.2d at 1156).

Under the learned intermediary doctrine, "a manufacturer will be held liable only where it fails to exercise reasonable care to inform a physician of the facts which make the drug likely to be dangerous." *Gurley v. Janssen Pharms.*, Inc., 113 A.3d 283, 292–93 (Pa. Super. Ct. 2015) (quoting *Cochran v. Wyeth*, Inc., 3 A.3d 673, 676 (Pa. Super. Ct. 2010)). Forearmed with adequate warnings from the manufacturer, the physician then takes on the responsibility to warn the patient. "[T]he determination of whether a warning is adequate is initially a question of law." *Ebert v. C.R. Bard, Inc.*, 459 F. Supp. 3d 637, 647 (E.D. Pa. 2020). "For a warning to be adequate as a matter of law . . . it must: (1) accurately and unambiguously convey the scope and nature of the risk, and (2) state the risk with sufficient specificity." *Schrecengost v. Coloplast Corp.*, 425 F. Supp. 3d 448, 462 (W.D. Pa. 2019). "[W]here fact questions exist (e.g., regarding the sufficiency of the warning for a particular risk identified in the label and whether the warning was diluted by marketing representations), the question of adequacy is one for the jury." *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 817 F. Supp. 2d 535, 545–46 (E.D. Pa. 2011). "The adequacy of a warning is determined based on what the manufacturer knew, or should have known, about a given risk at the time the patient was prescribed the medical device, and whether the label warned of that risk." *Ebert v. C.R. Bard, Inc.*, 459 F. Supp. 3d 637, 647 (E.D. Pa. 2020).

Defendants argue that summary judgment is appropriate because Dr. Schuricht testified during his deposition that "he was aware of the risks of hernia repair and ProLite, including risk of the conditions Plaintiff alleges she

sustained because of ProLite—seroma, infection, additional surgery, scar formation, pain, and hernia recurrence." (Def. St. ¶ 6; Pl. Resp. ¶ 6.) Defendants also rely on Dr. Schuricht's deposition testimony that the ProLite label "adequately warned [him] of the adverse reactions and complications that were possible with" ProLite and that "a different warning would not have impacted his treatment decisions." (Def. Br. p. 11–12; *see* Def. St. ¶¶ 7–8; Pl. Resp. ¶¶ 7–8.)

However, Dr. Schuricht also testified that, "[h]ad there been a risk the mesh was not sterile, he would not have used it." (Pl. Op. p. 6; *see* Pl. St. ¶¶ 5–6; Def. Resp. ¶¶ 5–6.)[6] Mills argues that "Dr. Schuricht assumed that the Atrium mesh he implanted in [her] was sterile" based on the IFU, which states: "Atrium Polypropylene Monofilament Surgical Mesh is a sterile, non-absorbable, knitted polypropylene monofilament mesh material for tissue reinforcement. . . . Atrium Mesh is contraindicated where tissue may be contaminated or infected . . . . Complications that may occur with the use of any surgical mesh include, but are not limited to, inflammation, infection or mechanical disruption of the tissue and/or mesh material, possible adhesions when placed in direct contact with the viscera (intestines)." (*See* Benak Decl. Ex. 31.)

Additionally, Mills asserts that Dr. Schuricht did not know about an October 11, 2012, warning letter from the Food and Drug Administration

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[6] Less pertinent is Mills's citation of Dr. Schuricht's tautological deposition testimony that he should have been warned about matters he should have been warned about:

> Q. [I]f there is additional risk that has not been described to you in these IFUs, or additional risk that you were not aware of them, based on knowledge within the medical community, would you like to know that before you decide to use this mesh? . . .
>
> A [by Dr. Schuricht]. Certainly if there are issues that should be known, I would like to know about them.

(Benak Decl. Ex. 22, Dr. Schuricht Dep. Tr. 107:16–108:5; *see* Pl. St. ¶ 7; Def. Resp. ¶ 7.)

("FDA") to Atrium (the "Warning Letter"), which states that, during an inspection of Atrium, FDA investigators noted violations, including "not adequately validat[ing] your current Ethylene Oxide (ETO) sterilization process that is used to sterilize all thirty nine (39) of your medica[l] devices." (Benak Decl. Ex. 3.; *see* Pl. St. ¶ 8; Def. Resp. ¶ 8; Ex. 22 Dr. Schuricht Dep. Tr. 110:1–10.).) After reviewing the Warning Letter and Atrium's "FDA Sterilization Response Quality Plan" (*see* Benak Decl. Exs. 3 and 4), Dr. Schuricht testified that, had he been aware of those documents, "it would have raised a level of concern," although assurances from the manufacturer and FDA, if given, might have allayed that concern:

> A [by Dr. Schuricht]. [B]ut I was not aware of this contemporaneous with Ms. Mills' surgery in March of 2013.
>
> Q. Yeah, I know, and . . . now that you've seen it, would that have impacted your decision to use the product? . . .
>
> A. You know, it would have raised a level of concern, but if I had the reassurances from the manufacturer and the FDA that the products that were currently out were safe and posed no risk to the patient, I would be happy and fine and comfortable to continue to use the product.
>
> Q. Okay. Did you ever seek assurances from the manufacturer or the FDA in case? . . .
>
> A. Personally, no.

(Benak Decl. Ex. 22, Dr. Schuricht Dep. Tr. 121:1–22.) According to Mills, "Dr. Schuricht's assumption that the mesh was sterile as represented by the manufacturer, renders his opinion at best unreliable and at worst meaningless." (Pl. Op. pp. 6–7.)

After review of the record, a genuine dispute remains regarding whether Dr. Schuricht would have altered his treatment decisions if he had received additional warnings that the mesh used during Mills's 2013 hernia repair surgery may not have been sterile. Mills cites, for example, FDA warnings about Atrium's sterile procedures, of which Dr. Schuricht was not aware. Although Dr. Schuricht testified that Mills's ProLite label "had adequate

warnings and a different warning would not have impacted his treatment decisions," he also testified that, if he had known about the Warning Letter and Atrium's "FDA Sterilization Response Quality Plan," "it would have raised a level of concern," even if hypothetical additional advice might have relieved that concern. (*See* Def. St. ¶ 8; Pl. Resp. ¶ 8; Benak Decl. Ex. 22, Dr. Schuricht Dep. Tr. 121:1–22.)

Therefore, because there are issues of fact that bear on whether the warning provided to Dr. Schuricht was adequate and whether a different warning would have altered Dr. Schuricht's decision, I will deny defendants' motion for summary judgment on Mills's negligent failure-to-warn claim.

2. Negligent Design Claim

Defendant moves for summary judgment on Mills's negligent design claim for lack of evidence of a safer alternative design. (Def. Br. p. 12.) As to this alternative negligence theory, Defendants' motion is granted.

To establish a negligent design claim under Pennsylvania law, "a plaintiff must demonstrate that the defendant breached its duty of care in designing the product, and that the breach caused her injuries." *Schrecengost v. Coloplast Corp.*, 425 F. Supp. 3d 448, 461 (W.D. Pa. 2019) (citing *Phillips v. Cricket Lighters*, 841 A.2d 1000, 1008 (Pa. 2003)). Specifically, the plaintiff must show that the defendant "failed to exercise reasonable care in the adoption of a safe design." *McGrain v. C.R. Bard, Inc.*, 551 F. Supp. 3d 529, 541 (E.D. Pa. 2021).

"To establish a breach of a duty of care, plaintiffs may, but are not required to, present evidence of a safer alternative design that the defendant could have adopted." *Schrecengost v. Coloplast Corp.*, 425 F. Supp. 3d 448, 461 (W.D. Pa. 2019) (citing *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 398 (Pa. 2014); *Lance v. Wyeth*, 85 A.3d 434, 458 n.36 (Pa. 2014)). In the extreme case where a plaintiff "proceed[s] under the theory that the product was too dangerous to market, then by definition no alternative design is necessary." *Spear v. Atrium Med. Corp.*, 621 F. Supp. 3d 553, 559 (E.D. Pa. 2022) (citing *Habecker v. Clark Equip. Co.*, 942 F.2d 210, 215 (3d Cir. 1991)). However, if a

plaintiff "argue[s] the product could have been marketed safely with better design, they will ultimately bear the burden of proving a feasible alternative design." *Id.* "To meet this requirement, a plaintiff must do more than 'baldly stat[e] that there are safer alternatives'; they must provide factual support demonstrating those alternatives exist." *Eng. v. Eisai, Inc.*, No. 21-cv-923, 2022 WL 780667, at *3 (M.D. Pa. Mar. 14, 2022) (quoting *Salvio v. Amgen, Inc.*, 810 F. Supp. 2d 745, 754 (W.D. Pa. 2011)).

Here, Mills does not dispute that she must show a feasible alternative design, and her brief confirms that she is basing her claim on the availability of such an alternative design:

> Defendant's conduct was not just negligent, it was intentional, willful and reckless. Knowing the raw material for its mesh products, including ProLite, was restricted by the manufacturer for implantation, knowing PPL tended to degrade in the body, knowing--as it must have--the existence of PVDF and its superior properties, it continued to sell a medical product for human implantation made from material it knew was not just questionable but prohibited, *when another potentially superior material was available*.

(Pl. Op. p. 17 (emphasis added).) Therefore, I will consider whether Mills has provided sufficient evidence of a feasible alternative design to survive summary judgment.

Mills relies on the deposition testimony of her expert Dr. Guelcher regarding the use of the material polyvinylidene fluoride ("PVDF") as an alternative to polypropylene, the material used for ProLite mesh. (Pl. Op. p. 15; *see* Pl. St. ¶¶45-48.) Defendants respond that Dr. Guelcher did not identify PVDF as a feasible alternative design.[7] (Def. Reply p. 13; *see* Benak Decl. Ex. 24 Dr. Guelcher Dep. Tr. 194:2–8, 195:4–196:2.)

[7] Defendants also assert, for the first time in their reply brief and without elaboration, that "an expert report cannot be backfilled at deposition." (Def. Reply p. 13 (citing *Bedell v. Long Reef Condo. Homeowners Ass'n*, 2014 WL 1715441, at *6 (D.V.I. 2014) and *Ciomber v. Coop. Plus, Inc.*, 527 F.3d 635, 642 (7th Cir. 2008)). In

The evidence in the record shows that Dr. Guelcher identified PVDF as a *potentially* better material than polypropylene for a mesh device but failed to offer any testimony to support that the use of PVDF is feasible. During his deposition, Dr. Guelcher acknowledged that the use of PVDF has not been fully investigated or tested on humans; he also refused to testify that PVDF was the "solution" without further testing:

Ciomber, the Seventh Circuit stated that later deposition testimony cannot be used to cure a deficient expert report:

> Rule 26(a)(2) does not allow parties to cure deficient expert reports by supplementing them with later deposition testimony. The purpose of Rule 26(a)(2) is to provide notice to opposing counsel—before the deposition—as to what the expert witness will testify, and this purpose would be completely undermined if parties were allowed to cure deficient reports with later deposition testimony. Allowing parties to cure a deficient report with later depositions would further undermine a primary goal of Rule 26(a)(2): "to shorten or decrease the need for expert depositions." After all, the parties' need for expert depositions would increase if they could use deposition testimony to provide information they should have initially included in their Rule 26(a)(2) report.

527 F.3d at 642 (internal citations omitted).

The U.S. Court of Appeals for the Third Circuit, however, does not automatically bar consideration of such evidence. *See Pritchard v. Dow Agro Scis.*, 263 F.R.D. 277, 282 & n.4 (W.D. Pa. 2009). When presented with a similar issue, the Third Circuit concluded that exclusion of critical expert evidence is an "extreme" sanction. *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 297 (3d Cir. 2012). Prior to excluding such evidence, the court must consider:

> (1) "the prejudice or surprise in fact of the party against whom the excluded witnesses would have testified" or the excluded evidence would have been offered; (2) "the ability of that party to cure the prejudice"; (3) the extent to which allowing such witnesses or evidence would "disrupt the orderly and efficient trial of the case or of other cases in the court"; (4) any "bad faith or willfulness in failing to comply with the court's order"; and (5) the importance of the excluded evidence.

Id. at 298; *see also Lamb v. Montgomery Township*, 734 F. App'x 106, 110–11 (3d Cir. 2018). None of these factors are addressed by defendant. Therefore, I will consider the deposition testimony of Dr. Guelcher on this basis, despite its suspect timing. I nevertheless find it lacking.

> Q. Okay. And you are not offering any opinions in this case that there is a different hernia device that would offer less severe potential complications, right?
>
> A [by Dr. Guelcher]. Well, I do believe that PVDF is potentially a better material for this device. It hasn't been fully investigated. I believe there are better options than polypropylene mesh because it changes after it's implanted, and that's unpredictable. The effects of it are unpredictable. . . . So it's not a great choice.
>
> Q. Okay. You are not testifying that PVDF would have less severe complications in total when you can't point to any studies or any use in humans, right?
>
> A: . . . I said it's less susceptible to these problems. They should be investigated as an alternative, but it's not, so --
>
> Q. You don't know if PVDF has other problems, because you don't know of any testing in humans, right?
>
> A. Well, it looks promising in the preclinical studies. In the human studies, they haven't been done, to my knowledge. So you would have to look for other problems. I can't say that it's the solution without the testing, but based on its material properties, I think it offers a lot of advantages. That's what I would say.

(Benak Decl. Ex. 24, Dr. Guelcher Dep. Tr. 205:5–206:13.)

> Q: You haven't seen any data as to how PVDF meshes perform in people, right?
>
> A: I can't remember any studies off the top of my head.
>
> Q: Okay. And so I assume you are not offering any opinion as to how PVDF performs in people, right?
>
> A: Well, that's not really true either. I believe based on two things; one, it is well known to be far less susceptible to oxidative polypropylene; two, if the clinical study showed really no measurable oxidative degradation, that would tell me that 'a potential candidate for clinical development, and making a mesh is going to be a better material. Now, there could be other problems that come up in clinical testing. I don't know, but at least based on those data, it certainly looks better opportunity, better material selection than polypropylene, but that has to be shown in clinical studies.

> Q: Okay. So your opinion is that it is a potential material, but you are not saying, I have looked at it and I am telling you it's my opinion that this is a better material to be used for hernia mesh.
>
> A: It could be, but it hasn't been studied in enough detail.

(*Id.* at 194:25–196:2.)

"Could be" won't cut it. The question here is whether "an alternative, *feasible*, safer design" would have lessened Mills's injury. *See Salvio*, 810 F. Supp. at 754 (emphasis added). Identifying PVDF as an alternative material is not enough; Mills must provide some factual support that such an alternative exists. *See id.* Mills has failed to do so. Defendants have demonstrated the absence of evidence of feasibility of using PVDF as an alternative to polypropylene. Mills has not responded with any evidence that her proffered alternative design is feasible.

To turn the argument around, plaintiff is claiming that to avoid a claim of negligent design, the manufacturer was required to employ an untested alternative. That is not a viable, acceptable standard of care.

Because there is a failure of proof concerning whether Mills's proffered alternative design is feasible, which is a required element, summary judgment is granted in favor of Atrium and Maquet on the negligent design claim.

IV. CONCLUSION

For the reasons set forth above, Atrium and Maquet's motion for summary judgment is **GRANTED in part and DENIED in part**.

An appropriate order follows.

Dated: June 22, 2023

/s/ Kevin McNulty

Hon. Kevin McNulty
United States District Judge